



Standard Operating Procedures

6.5.2 Re-screening ©2008

History			
Version	Date	Author	Reason
1.1	18 th July 2007	B Fazekas	New procedure
1.2	8 th January 2008	B Fazekas	Update following MAB review
1.3	19 th February 2008	B Fazekas	Update after review by D Currow

Approval				
Version	Author	Signature	Approval Name	Approval Signature
1.3	B Fazekas	<i>B. Fazekas</i>	D Currow (CI)	<i>D. Currow</i>

Scheduled review

Date August 2009

Responsible person PaCCSC Project Officer

6.5.2 Re-screening

Purpose

People potentially eligible for the PaCCSC studies will be screened in accordance with protocol specific procedures. This process will ensure that people are fully screened, and enter studies after having met all of the criteria. The procedure detailed in 6.5.1 Study Recruitment SOP should be followed. There are some circumstances where people can be re-screened at a later date for the study after having already been screened initially.

This SOP will outline the circumstances when re-screening is appropriate and how this is to be recorded.

Other related SOPs

- 5.5.5 Allocation of Participant ID Numbers
- 6.5.1 Study recruitment
- 5.23.2 CRF completion

Attachments

CRF-A front page example

References

Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95). Annotated with TGA comments 2000 (accessed 250207)
<http://www.tga.gov.au/docs/pdf/euguide/ich/ich13595.pdf>

Acknowledgments

Trans-Tasman Radiation Oncology Group (TROG), for generous access to the Policy and Procedure Manual – the Red Book.

Definitions

Case Report Form (CRF) A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each trial subject. All events described within the study protocol should be captured the CRF.

Inclusion criteria

A list of requirements, that individuals must meet, in order to be eligible to participate in the study.

Independent Ethics Committee (IEC)/Human Research Ethics Committees (HREC)/Institutional Review Board (IRB)

An independent body (a review board or committee, institutional, regional, national or supranational), duly constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of participants involved in a trial and to provide public assurance of that protection by, among other things, reviewing and approving/providing acceptance opinion on the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the participants. (Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95). Annotated with TGA comments 2000).

Informed Consent

A process by which a person voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to that person's decision to participate. Informed consent is documented by a written, signed and dated consent form, unless otherwise dealt with in an institutional ethics approved trial protocol.

Exclusion criteria

A list of requirements, any of which will exclude the person from participating in the study.

Screen Failure

Where the person has provided consent after being fully informed of the study, and has been found ineligible, either because the inclusion criteria have not been met, or an exclusion criteria was met.

Screening

Screening involves collection of information that is in addition to clinical care, it is collected for the reason of assessing eligibility for the study. These assessments may be testing for cognition, level of function, taking blood samples, requesting medication history, etc. As such this information is always collected after consent has been obtained.

Procedure

Screening and consent

Screening for eligibility takes place after the broad entry characteristics have been met as part of the Pre-screening. It is at this point that the study is fully explained, using the approved Patient Information Sheet and Consent Form. The person's consent is obtained according to the study protocol, and the eligibility assessments are undertaken.

Following screening, people either proceed to randomisation, or do not meet the criteria, and are a screen failure. This is recorded in the patient master index at each site, and is to be reported as part of the Key Performance Indicators for that site.

The consent and screening procedures will vary slightly between studies, and are described within the study protocols. These procedures are to be followed in order to comply with GCP requirements.

Re-Screening

In some cases it is possible that people will need to be re-screened, for example

- If a person consents to participate, meets the eligibility criteria but there is a delay in starting due to a change in situation (family issues, individual request for attending private matter, etc).
- If the person previously failed eligibility due to an acute event that has now resolved, or
- Medications have now stabilised
- Reversible causes of screen failure have been adequately treated. If someone has a reversible issue that currently precludes involvement (for example anaemia) and this is corrected (for example by transfusion), they should be re-screened.

Procedure

In these situations, if randomisation has not occurred;

- A new Case Report Form -A form is used
- A new Identification number is assigned to the person (the 3 digit patient number), see 5.5.5 Allocation of Participant ID Numbers.
- The person is flagged as having been re-screened on both the Case Report Form -A and the site master list
- The Case Report Form -A is completed as if being fully screened, data is not copied from one form to the next, but completed using the current clinical situation as documented within the patient clinical notes.
- The person may need to sign a new consent form as part of the screening procedure.

It is not appropriate to re-screen a patient if they have previously failed to meet the eligibility criteria and there have been no further changes or treatments that would now indicate that the patient may be suitable.